TF “(nano) TiO2 safety communication”

Prof. dr. Damjana Drobne, University of Ljubljana, Slovenia

damjana.drobne@bf.uni-lj.si
http://www.bionanoteam.com/
Content

• Introduction

• Report

• Conclusions and Future challenges
Introduction
European Commission publishes titanium dioxide classification

19-Feb-2020 By Nathan Gray

After almost a decade of work, the European Commission has published its final decision to classify titanium dioxide as a category 2 carcinogen.

HTTPS://WWW.COSMETICSDESIGN-EUROPE.COM/ARTICLE/2020/02/19/EUROPEAN-COMMISSION-PUBLISHES-TITANIUM-DIOXIDE-CLASSIFICATION

https://www.cosmeticsdesign-europe.com/Article/2020/02/19/European-Commission-publishes-titanium-dioxide-classification
“Suspected of causing cancer through inhalation” (H351)

The regulation mandates that by October 1, 2021 hazard labels will be required on certain TiO2 powder products and certain powder mixtures containing TiO2 put on the market in the European Union.
Objection regarding scientific evidence

This classification of TiO2 is not based on latest scientific insights but instead on older animal test data.

https://chemicalwatch.com/92936/publication-of-eu-titanium-dioxide-classification-law-imminent#overlay-strip
In January 2018, NSC launched a task force “(nano) TiO$_2$ safety communication” (TF for TiO$_2$) with the aim to adequately and accurately cover the scientific findings regarding TiO$_2$ and TiO$_2$ nano safety and to provide independent and transparent scientific opinion and advice to stakeholders.
Task Force: (nano) TiO2 safety communication
Landscape

Regulation (ECHA)

Science (Knowledge)

Policy (EU parliament)

TiO2, nanoTiO2, products and producers
Science meets society...

Where science meets society: putting risk assessment in context

Values are becoming more influential than facts. Discussions about risks are increasingly politicised. How can we restore trust in science? #EFSA2018

4:50 pm · 3 May 2018 · Hootsuite
A need

Science (Knowledge) visibility

Regulation (ECHA)

Policy EU parliament

TiO2, nanoTiO2, products and producers
Contribution of TF for (nano)TiO2 communication: Increasing visibility of scientific knowledge

Scientific knowledge
CLP regulation process
In May 2016, The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) submitted the **Harmonised Classification and Labelling (CLH) report for TiO$_2$** to the European Chemical Agency (ECHA).
CLH report
Proposal for Harmonised Classification and Labelling Based on Regulation (EC) 1272/2008 (CLP Regulation), Annex VI, Part 2

Substance Name: Titanium dioxide

EC Number: 236-675-5
CAS Number: 13463-67-7
Index Number: -
Contact details for dossier submitter:

ANSES (on behalf of the French MSCA)
Ministries of Consumer Affairs, Health, Labour, Ecology and Agriculture
14 rue Pierre Marie Curie
F-94701 Maisons-Alfort Cedex
reach@anses.fr
Version number: 2 Date: May 2016
Phase I: The Committee for Risk Assessment (RAC) prepares the opinions for ECHA related to the risks of substances to human health and the environment.

Phase II: ECHA sends this to the European Commission, which will decide what, if any, regulatory measures should be taken.

Phase I: Proposal for Harmonised Classification and Labelling

Substance TiO$_2$

The final decisions are taken by the European Commission (if approved, ATP publication follows).
ANSES submits Proposal for Harmonized Classification and Labelling
May 2016

Comments submitted to ECHA during public consultation
(45 days)
July and August 2016

ECHA’s RAC committee submits opinion
9 June 2017

CARACAL meeting: comments by MSs
15-16 November 2017

CARACAL meeting comments by MSs
7-8 March 2018

Additional public consultation
ECHA closed on 8th Feb 2019

CARACAL meetings followed June 2018
2019

Final decision made by EC February 2020
On **February 18, 2020** the European Union published the delegated regulation classifying certain powder titanium dioxide (TiO2) and powder mixtures containing TiO2 as a **suspected carcinogen (Category 2)** via inhalation under its EU Regulation No 1272/2008 on classification, labelling and packing (CLP) of substances and mixtures. The regulation mandates that by **October 1, 2021** hazard labels will be required on certain TiO2 powder products and certain powder mixtures containing TiO2 put on the market in the European Union.

https://www.cosmeticsdesign-europe.com/Article/2020/02/19/European-Commission-publishes-titanium-dioxide-classification

Beyond

The burden of the unresolved circular economy issues will fall on the Member States

The Commission acknowledged that the CLP classification of TiO$_2$ would have unintended impacts on the circular economy and the EU put efforts to address the issue by proposing an update to the guidance on the classification of waste (CA/23/2019). The guidance is not legally binding and thus it is insufficient to avoid negative impacts on the circular economy. It is unclear when, and if, the update of the guidance will be completed, and no legislative changes are expected in the short to medium term to resolve the issue.
Report
The key argument against the submitted CLH for TiO₂

- “carcinogenicity profile described for TiO₂ is not exclusively characteristic for TiO₂ but applies to the whole group of chemicals referred to as poorly soluble low toxicity (PSLT) particles,”, as acknowledged also by ECHA/RAC (https://chemycal.com/news/b77b853d-21e6-44e4-ac63-2873ce3cb75a/VCI_Statement_on_the_Proposal_for_a_Harmonised_Classification_of_Titanium_dioxide).

- Guidance on the Application of the CLP Criteria (Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures; Version 5.0 July 2017). The guidance clearly states the need for „considerations of all other relevant information (weight of evidence and expert judgement of all most up to date information and knowledge is performed) being taken into account as appropriate.“ not just that given in the dossier. There is a need to update and reconsider the information given in the CLP dossier (see page 376, 3.6.1. Definitions and general considerations for classification for carcinogenicity).
Postulated **adverse outcome pathway of TiO2 related to carcinogenicity** after *inhalation* *exposure*. The suggested AOP leading to lung tumors is *operative in rats*. Abbreviations: KE, key event; ROS, reactive oxygen species; TiO2, titanium dioxide.


[https://doi.org/10.1146/annurev-pharmtox-101419-100049](https://doi.org/10.1146/annurev-pharmtox-101419-100049)
Conclusions and Future challenges
How to Make the Right Data-Driven Decisions

Cooper (2014) defines wisdom as “an extrapolative process which includes knowledge in an ethical and moral framework”.


https://blog.stratasan.com/data-driven-decisions-dikw-pyramid
The aim of the risk assessment is to evaluate the significance of the risk by reference to a societal norm, standard or view on its acceptability, and then make organisational and individual arrangements for its active management.

“Green Leaves III”, 2011 Guidelines for Environmental Risk Assessment and Management.
Continuation....

NMBP-13 science-based risk governance of nanomaterials
Future

Science (Knowledge)

Nano Risk governance Council*

Regulation (ECHA)

nanotechnologies

Policy EU parliament

*bringing in an ethical and moral framework
The key aspects TF has ‘discovered’ that was otherwise overlooked by the wider community

Science has to meet society...

....to Make the Right Data-Driven Decisions.
Future

TF contributors

A list of active TF contributors:

1. Marie Carriere; CEA, France marie.carriere@cea.fr
2. Albert Duschl; Universität Salzburg albert.duschl@sbg.ac.at
3. Fred Klaessig; Pennsylvania Bio Nano Systems fred.klaessig@verizon.net
4. Paul Kiekens University Gent [mailto: Paul.Kiekens@UGent.be]
5. Camille de Garidel-Thoron [mailto: cgaridel@cerege.fr]
6. Warheit David david.warheit@gmail.com
7. Dana Kühnel GmbH – UFZ dana.kuehnel@ufz.de
8. Damjana Drobne, University Ljubljana Damjana.drobne@bf.un-lj.si

Many others....

A reviewer:
9. 22/04/2019 Quick social science review of part II by Claire Mays (reviewer)

https://www.nanosafetycluster.eu/nsc-overview/nsc-structure/task-forces/tf-tio2/
Thank you for attention

Questions?